

PUBLIC HEALTH DEPARTMENT[641]

Notice of Intended Action

Twenty-five interested persons, a governmental subdivision, an agency or association of 25 or more persons may demand an oral presentation hereon as provided in Iowa Code section 17A.4(1)“b.”

Notice is also given to the public that the Administrative Rules Review Committee may, on its own motion or on written request by any individual or group, review this proposed action under section 17A.8(6) at a regular or special meeting where the public or interested persons may be heard.

Pursuant to the authority of Iowa Code section 136A.8, the Department of Public Health hereby gives Notice of Intended Action to amend Chapter 4, “Center for Congenital and Inherited Disorders,” Iowa Administrative Code.

The proposed amendments revise the time line for the development of policies and procedures for obtaining informed consent for the storage and release of residual newborn screening specimens and clarify the use of linked specimens in feasibility studies approved by the Congenital and Inherited Disorders Advisory Committee (CIDAC) for the purpose of incorporating new tests or evaluating new test methodologies when the clinical validity and reliability of the test methodologies have previously been determined. The proposed amendments also replace the defunct Iowa Registry for Congenital and Inherited Disorders (IRCID) Internal Advisory Committee with CIDAC for the review of proposals for research and correct a typographical error in rule 641—4.11(136A).

These proposed amendments have been reviewed by the Congenital and Inherited Disorders Advisory Committee and interested individuals within the field.

Any interested person may make written suggestions or comments on these proposed amendments on or before December 29, 2015. Such written comments should be directed to Kimberly Noble Piper, State Genetics Coordinator, Center for Congenital and Inherited Disorders, Department of Public Health, Lucas State Office Building, 321 East 12th Street, Des Moines, Iowa 50319; fax (515)725-1760. E-mail may be sent to kimberly.piper@idph.iowa.gov.

After analysis and review of this rule making, no impact on jobs has been found.

These amendments are intended to implement Iowa Code chapter 136A.

The following amendments are proposed.

ITEM 1. Amend paragraph 4.3(2)“e” as follows:

e. Informed consent for the storage and release of residual specimens for research use. ~~The By July 1, 2017, the department shall establish policies and procedures, including an informed consent procedure for the storage and release of specimens for research, to allow a parent or guardian the ability to provide informed consent prior to the release of the newborn’s residual newborn screening specimen for research purposes. The parent or guardian, birthing facility or attending health care provider shall submit the informed consent form documentation of informed consent to the central laboratory state hygienic laboratory or its designee pursuant to established policy and procedure. The informed consent procedure shall apply to all specimens collected on or after January 1, 2016 July 1, 2017. For specimens collected prior to January 1, 2016 July 1, 2017, a parent or guardian may send a letter stating that the newborn’s specimen is not to be released for research purposes. This letter shall include the parent’s or guardian’s name, the newborn’s name at birth, and the newborn’s date of birth. The letter of notice shall be sent to the State Hygienic Laboratory at Newborn Screening Program, State Hygienic Laboratory, 2220 S. Ankeny Blvd., Ankeny, Iowa 50023-9093 state genetics coordinator at the Iowa Department of Public Health, 321 East 12th Street, Des Moines, Iowa 50319-0075.~~

ITEM 2. Amend paragraph 4.3(8)“c” as follows:

c. Research. A residual newborn screening specimen may be released for research purposes only if ~~written~~ informed consent has been received from a parent or guardian of the child, or the individual adult upon whom the screening was performed, and each of the following conditions is satisfied:

(1) to (3) No change.

ITEM 3. Amend paragraph **4.3(8)“d”** as follows:

d. Newborn screening program operations. Residual newborn screening specimens may be used for activities, testing, and procedures directly related to the operation of the newborn screening program, including confirmatory testing, laboratory quality control assurance and improvement, calibration of equipment, evaluation and improvement of the accuracy of newborn screening tests, and validation of equipment and screening methods, and the use of linked specimens in feasibility studies approved by the Congenital and Inherited Disorders Advisory Committee for the purpose of incorporating new tests or evaluating new test methodologies when clinical validity and reliability of the test methodologies have previously been determined.

ITEM 4. Amend subparagraphs **4.7(6)“e”(1)** and **(2)** as follows:

(1) All proposals for research using the IRCID data to be conducted by persons other than program staff shall first be submitted to and accepted by the researcher’s institutional review board. Proposals shall then be reviewed and approved by CIDAC and the department ~~and the IRCID’s internal advisory committee~~ before research can commence.

(2) The IRCID shall submit to ~~the IRCID’s internal advisory committee~~ CIDAC and the department for approval a protocol describing any research conducted by the IRCID in which the IRCID deems it necessary to contact case subjects and controls.

ITEM 5. Amend rule 641—4.11(136A), introductory paragraph, as follows:

641—4.11(136A) Purpose. CIDAC represents the interests of the people of Iowa and assists in the development of programs that ensure the availability of and access to quality genetic and genomic health care services by all residents. The committee advises the director regarding issues related to genetics and hereditary and ~~congenital~~ congenital disorders.